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09/394,006 09/10/99 BERGER

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EXAMINER

HM22/0313

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FORMAN, B

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

03/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/394,006

Applicant(s)

BERGER ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892) 17) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 18) ☐ Notice of Informal Patent Application (PTO-152)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 19) ☐ Other: _____

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DETAILED ACTION

Specification

1. The spacing of the lines of the specification is such as to make reading and entry of amendments difficult. New application papers with lines double spaced on good quality paper are required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 6 & 13 - 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bresser et al. (U.S. Patent No. 5,521,061, files 17 July 1992).

Regarding Claim 1, Bresser et al. disclose a composition comprising a first substance capable of precipitating comprising at least one alcohol or ketone and a second substance to aid in the infusion of the first substance i.e. DMSO (Column 2, lines 50-55 and Claim 1).

Regarding Claim 2, Bresser et al. disclose the composition wherein the alcohol is selected from ethanol, propanol, isopropanol and butanol (Claim 2, line 48).

Regarding Claim 3, Bresser et al. disclose the composition wherein the second substance is dimethyl sulfoxide (Claim 1, line 25).

Regarding Claim 4, Bresser et al. disclose the composition wherein the first substance is comprised of a precipitating agent i.e. alcohol (Claim 54, line 3). Bresser et al. disclose the composition wherein the precipitating agent is dithiothreitol and the second substance is polyethylene glycol (Column 8, lines 65-68 and Column 9, lines 1-5).

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Regarding Claim 6, Bresser et al. disclose the composition wherein the first substance is comprised of a first alcohol i.e. dithiothreitol and a second alcohol i.e. polyethylene glycol (Column 9m lines 6-17).

Regarding Claim 13, Bresser et al. disclose the nucleic acid is DNA (Column 6, line 45).

Regarding Claim 14, Bresser et al. disclose the nucleic acid is RNA (Column 6, line 47-48).

Regarding Claim 15, Bresser et al. disclose the nucleic acid is ribosomal RNA (Column 6, line 48).

Regarding Claim 16, Bresser et al. disclose the cell is a prokaryote or eukaryote (Column 6, lines 14-15).

Regarding Claim 17, Bresser et al. disclose the cell is a microorganism (Column 6, line 17).

Claim Rejections - 35 USC § 102/103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 5, 9 & 11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bresser et al. (U.S. Patent No. 5,521,061, files 17 July 1992) as applied to Claim 1 above. Bresser et al. disclose a composition comprising a first substance capable of precipitating comprising at least one alcohol or ketone and a second substance to aid in the infusion of the first substance i.e. DMSO (Column 2, lines 50-55 and Claim 1).

Regarding Claim 5, Bresser et al. do not teach a 4:1 ratio of the first and second substance. However, Bresser et al. teach the composition wherein 2-20 percent of the composition is said first substance i.e. an alcohol and wherein 2-20 percent of the composition is said second substance i.e. dimethyl sulfoxide. It would have been known to one of ordinary skill in the art that the percentages taught by Bresser et al. include the 4:1 ratio e.g. 8%:2% or 12%:3% etc.

Regarding Claim 9, Bresser et al. disclose the composition wherein said first substance is a precipitating agent i.e. alcohol and said second substance is dimethyl sulfoxide (Claim 54, lines 1-3). It was known to one of skill in the art at the time the claimed invention was made that methanol is a precipitating agent as taught by Bresser et al. (Column 7, line 40).

Regarding Claim 11, Bresser et al. disclose the composition wherein said first substance is a precipitating agent i.e. alcohol and said second substance is dimethyl sulfoxide (Claim 54, lines 1-3). It was known to one of skill in the art at the time the claimed invention was made that ethanol is a precipitating agent as taught by Bresser et al. (Column 7, line 40).

It would have been obvious to one of ordinary skill in the art that the ratio recited in Claim 5 is deemed to be inherent in the 2 to 20% concentration recited in Bresser et al. because it would have been obvious to the skilled practitioner that the 2 to 20% recited by Bresser et al. encompasses the claimed ratio of 4:1. Additionally, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the

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precipitating agent teaching of Bresser et al. to the composition of Bresser et al. because the skilled practitioner would have inferred from the specific teaching of Bresser et al. wherein the precipitating agent is an alcohol and the alcohol is selected from the group consisting of ethanol and methanol that either ethanol or methanol would function as precipitating agents in the composition taught by Bresser et al. Therefore the skilled practitioner would have been motivated to use ethanol or methanol in the composition at the ratio of 4:1 based on cell type being assayed, available reagents and known precipitating properties.

7. Claims 7 & 10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bresser et al. (U.S. Patent No. 5,521,061, filed 17 July 1992) as applied to Claims 1 & 6 above. Bresser et al. disclose a composition comprising a first substance capable of precipitating comprising at least one alcohol or ketone and a second substance to aid in the infusion of the first substance i.e. DMSO (Column 2, lines 50-55 and Claim 1) and wherein the first substance is comprised of a first alcohol i.e. dithiothreitol and a second alcohol i.e. polyethylene glycol (Column 9m lines 6-17).

Regarding Claim 7, Bresser et al. do not teach the composition wherein the ratio of the first and second substances are 2.5:2.5:5. However, Bresser et al. teach the composition wherein 2-20 percent of the composition is said first substance i.e. an alcohol and wherein 2-20 percent of the composition is said second substance i.e. dimethyl sulfoxide. It would have been known to one of ordinary skill in the art that the percentages taught by Bresser et al. include the 2.5:2.5:5 ratio e.g. 2%:2%:5% or 4%:4%:16% etc.

Regarding Claim 10, Bresser et al. disclose the composition wherein said first substance is a precipitating agent i.e. alcohol and said second substance is dimethyl sulfoxide (Claim 54, lines 1-3). It was known to one of skill in the art at the time the claimed invention was made

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that ethanol and methanol are precipitating agents as taught by Bresser et al. (Column 7, line 40).

It would have been obvious to one of ordinary skill in the art that the ratio recited in Claim 7 is deemed to be inherent in the 2 to 20% concentration recited in Bresser et al. because it would have been obvious to the skilled practitioner that the 2 to 20% concentration for both the first and second substance recited by Bresser et al. encompasses the claimed ratio of 2.5:2.5:5. Additionally, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the precipitating agent teaching of Bresser et al. to the composition of Bresser et al. because the skilled practitioner would have inferred from the specific teaching of Bresser et al. wherein the precipitating agent is an alcohol and the alcohol is selected from the group consisting of ethanol and methanol that ethanol and methanol would function as precipitating agents in the composition taught by Bresser et al. Therefore the skilled practitioner would have been motivated to use ethanol and methanol in the composition at the ratio of 2.5:2.5:5 based on cell type being assayed, available reagents and known precipitating properties.

8. Claims 8 & 12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bresser et al. (U.S. Patent No. 5,521,061, filed 17 July 1992) as applied to Claim 1 & 4 above. Bresser et al. disclose a composition comprising a first substance capable of precipitating comprising at least one alcohol or ketone and a second substance to aid in the infusion of the first substance i.e. DMSO (Column 2, lines 50-55 and Claim 1) wherein the first substance is dithiothreitol and the second substance is polyethylene glycol (Column 8, lines 65-68 and Column 9, lines 1-5).

Regarding Claim 8, Bresser et al. do not teach a 1:1 ratio of the first and second substance. However, Bresser et al. teach the composition wherein 2-20 percent of the

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composition is said first substance i.e. an alcohol and wherein 2-20 percent of the composition is said second substance i.e. dimethyl sulfoxide. It would have been known to one of ordinary skill in the art that the percentages taught by Bresser et al. include the 1:1 ratio.

Regarding Claim 12, Bresser et al disclose the composition wherein said first substance is a precipitating agent i.e. alcohol and said second substance is dimethyl sulfoxide (Claim 54, lines 1-3). It was known to one of skill in the art at the time the claimed invention was made that methanol is a precipitating agent as taught by Bresser et al. (Column 7, line 40).

It would have been obvious to one of ordinary skill in the art that the ratio recited in Claim 8 is deemed to be inherent in the 2 to 20% concentration recited in Bresser et al. because it would have been obvious to the skilled practitioner that the 2 to 20% recited by Bresser et al. encompasses the claimed ratio of 1:1. Additionally, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the precipitating agent teaching of Bresser et al. to the composition of Bresser et al. because the skilled practitioner would have inferred from the specific teaching of Bresser et al. wherein the precipitating agent is an alcohol and the alcohol is selected from the group consisting of ethanol and methanol that methanol would function as a precipitating agent in the composition taught by Bresser et al. Therefore the skilled practitioner would have been motivated to use methanol in the composition at the ratio of 1:1 based on cell type being assayed, available reagents and known precipitating properties.

It is noted that *In re Best* (195 USPQ 430), *In re Spada* 15 USPQ2d 1655 and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes properties that are newly cited or is identical to a product instantly claims. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

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Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
March 9, 2000

S. Forman
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